UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,224	10/27/2000	Peter A. Rice	BOS/3	8386

1473 7590 02/26/2003

FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020-1105

EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	13

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/699,224	Rice et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 12, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/~~are~~ pending in the application.

4a) Of the above, claim(s) *17-31* is/~~are~~ withdrawn from consideration.

5) ☒ Claim(s) *16* is/~~are~~ allowed.

6) ☒ Claim(s) *1-15* is/~~are~~ rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4 & 5.*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 06/17/02 (paper no. 9) and 12/12/02 (paper no. 12).

It is noted that a marked-up version of the amendment introduced to claim 27 was not submitted along with the response filed 12/12/02 (paper no. 12) in compliance with 37 C.F.R. 1.121. The clean version is currently entered into the case. Applicants should avoid this sort of non-compliance in future in order to prevent issuance of a Notice of non-compliant Amendment under 37 C.F.R 1.121.

Election

2) Acknowledgment is made of Applicants' election filed 12/12/02 (paper no.12), with traverse (in part), of invention 1, claims 2 and 16, in response to the restriction requirement mailed 11/12/02 (paper no. 11).

Applicants contend that there is no search burden to examine the subject matter of the inventions. Applicants cite MPEP § 803 and submit that for a restriction requirement to be proper, the inventions must be independent or distinct, and that there must be a serious burden on the Office if restriction were not required. Applicants further state that if the search and examination of an entire application can be made without serious burden, it must be examined on the merits even though it includes claims to distinct or independent inventions. Applicants assert that the claims of inventions 9-12 share the common novel element of peptide mimics. Applicants state that a search for the peptide mimics of claims 1-3 and 11-14 alone would necessarily be co-extensive with a search for the methods employing the peptide mimics of claims 24 and 25, and would therefore not impose a serious burden. Applicants submit similar arguments with regard to the inventions 10-12.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion and as clearly set forth in the restriction requirement mailed 11/12/02 (paper no. 11), each SEQ ID number encompassed in inventions 1 through 8 represents a structurally distinct product, each requiring a separate sequence or structural search, despite the fact that they are placed in the same class/subclass. Clearly, a structural search performed for one SEQ ID number would not be co-extensive to another SEQ ID number. This would undoubtedly impose a serious

burden on the Office. Inventions 1-8 and invention 9 as well as inventions 10 and 11, are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the peptide mimic or the conjugate or complex can be used in a materially different process, for example, as a coating antigen in an *in vitro* diagnostic assay. With regard to burden of search and examination, MPEP 803 states that a restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and *examination burden* is placed on the Examiner if restriction is not required. In the instant application, in addition to a search burden that necessitates non-coextensive searches of issued US patents and the non-patent literature, an examination burden is quite apparent. For these reasons, the restriction requirement mailed 11/12/02 is proper and is hereby made FINAL.

Status of Claims

3) Claim 27 has been amended via the amendment filed 12/12/02.

Claims 1-31 are pending in this application.

Claims 17-31 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

The elected claims 2 and 16, and the linking claims 1 and 3-15 are under examination.

Sequence Listing

4) Acknowledgment is made of Applicants' Sequence Listing filed 06/17/02 (paper no. 9) which has been entered on 06/28/02 (paper no. 10).

Information Disclosure Statements

5) Acknowledgment is made of Applicants' information disclosure statements filed 03/07/01 and 01/02/02 (paper no. 4 and 5). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 13).

Drawings

6) The drawings are objected to under 37 C.F.R 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 13). Correction is required. Applicant is

asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 C.F.R 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 C.F.R 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

Priority

7) This application claims domestic priority to the provisional application, SN 60/162,491, filed 10/29/1999.

Specification - Informalities

8) The specification is objected to for the following reasons:

(a) The first paragraph on page 1 of the specification does not information about the provisional application as indicated in italicized letters in the paragraph above under 'Priority'. Correction is requested.

(b) The amino acid sequence recited in line 13 on page 18 and those recited in Figure 2 contain more than four amino acids, yet are not identified by a SEQ ID NO. as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

(c) Under 'Brief Description of the Drawings' on page 9, the recitation "Figure 8 shows" should be replaced with --Figures 8A-8D show--. All references to this Figure in the specification should be amended to reflect this change in numbering.

(d) The use of the trademark in the instant specification has been noted. For example, see page 18, last paragraph: "tween-20"; and page 17, line 7: "CellQuest". The recitations should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their

validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

Rejection(s) under Double Patenting

9) The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

10) Claims 1, 3 and 9-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of US patent 5,476,784 (Rice *et al.*) ('784), claims 1-9 and 11 of US patent 5,939,067 (Rice *et al.*) ('067), and claims 1-4 of the US patent 6,099,839 (Rice *et al.*) ('839).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998)*; *In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)*; *In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir, 1985)*.

Claims 1-3 and 6 of US patent 5,476,784, claims 1-9 and 11 of US patent 5,939,067 and claims 1-4 of US patent 6,099,839 recite or encompass the binding fragment of an anti-idiotypic monoclonal antibody or the antibody itself and/or a composition comprising an

immunoprophylactically effective amount of the same, which immunospecifically binds to the idiotype of a second antibody which binds to an oligosaccharide epitope of *N. gonorrhoeae* which epitope is not present in human blood group antigens, wherein the oligosaccharide epitope specifically binds to monoclonal antibody 2C7 produced by a hybridoma cell line having the characteristics of HB-11311 as deposited with the ATCC. Claims 1, 3 and 9-15 cannot be considered patentably distinct over the above-identified claims of US patents '784, '067 and '839, which specifically recite or encompass the binding fragment of an anti-idiotypic monoclonal antibody, or the antibody itself and/or a composition comprising the same, which immunospecifically binds to the idiotype of a second antibody which binds to an oligosaccharide epitope of *N. gonorrhoeae* which epitope is not present in human blood group antigens, wherein the oligosaccharide epitope specifically binds to monoclonal antibody 2C7 produced by a hybridoma cell line having the characteristics of HB-11311 as deposited with the ATCC, and would anticipate the instant claims.

Rejection(s) under 35 U.S.C. § 101

11) Claims 1 and 11, and claims dependent therefrom are rejected under 35 U.S.C. § 101 as being directed to a non-statutory subject matter. The claims read on a product of nature, i.e., naturally occurring peptide mimics. Claims 1 and 11 lack limitations which distinguish the product from those that may exist naturally. Consequently, the claims do not embody patentable subject matter as defined in 35 U.S.C § 101. See MPEP 2105. It is suggested that Applicants use a limitation, such as, --isolated peptide mimic-- in connection with the peptide product to reflect the hands of the inventors in the production or creation of the recited product as is supported, for instance, on page 18 of the instant specification.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

12) Claims 2, 4-10 and 13-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 10 is vague and indefinite in the abbreviated recitation "LOS", because it is unclear what is encompassed in this abbreviation. It is suggested that Applicants use the full terminology at first occurrence while retaining the abbreviation within parentheses.

(b) Claim 13 is vague and indefinite in the recitation "the characteristics of HB 11311"

because it is unclear what characteristics are encompassed in this limitation.

(c) Claims 9 and 14 are vague and indefinite in the recitation "multiple antigen peptide", because it is unclear what is encompassed in this limitation. Does it mean that the peptide mimic comprises multiple antigens, or that it is present within a larger protein or polypeptide? Clarification/correction is requested.

(d) Claim 2 is vague and indefinite in the recitation "DE_GLF", because it is unclear what does '_' represent. Does this represent a gap which does not have to have an amino acid residue, or does it represent a space which has to contain one or more specific or non-specific amino acid residues? Clarification/correction is requested.

(e) Claim 6 is vague in the recitation "tail", because it is unclear what it contains or what its composition is. Does it contain one or more amino acid residues, a carbohydrate, or a fusion protein or peptide?

(f) Claims 4-10 and 15, which depend directly or indirectly from a base claim identified above, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

13) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> **(e)** The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14) Claims 1, 3 and 9-15 are rejected under 35 U.S.C. § 102(e) as being anticipated by Rice *et al.* (US 6,099,839) ('839).

Rice *et al.* ('839) disclosed fragments of anti-idiotypic antibodies and antibodies themselves which immunospecifically bind to antibodies that recognize oligosaccharide epitopes of *N. gonorrhoeae* which are not present in human blood group antigens and a composition comprising an immunoprophylactically effective amount of the same. The fragments retain the antigen binding

specificity and react with an idiotype that is directed against an oligosaccharide antigen of *N. gonorrhoeae*. The anti-idiotypic monoclonal antibody is produced by the hybridoma cell line HB 11311 deposited at the ATCC. The fragments are for administration to individuals to induce a specific immune response directed against gonococci or cells bearing the specific oligosaccharide antigen. See claims; paragraph bridging columns 3 and 4; column 5, lines 30-37; column 7, lines 41-46 and lines 55-60; sections II(a) and II(b) in columns 21 and 22; and first and second paragraphs in column 28. That the prior art binding fragments intrinsically serve as peptide mimics being capable of inducing a T-cell dependent immune response is inherent from the teachings of Rice *et al.* ('839). Rice's ('839) whole anti-idiotypic antibody comprising the binding fragment is viewed as the multiple antigen peptide.

Claims 1, 3 and 9-15 are anticipated by Rice *et al.* ('839).

15) Claims 1, 3 and 9-15 are rejected under 35 U.S.C. § 102(e) or 102(a) as being anticipated by Rice *et al.* (US 5,939,067) ('067).

Rice *et al.* ('067) disclosed fragments of anti-idiotypic antibodies and antibodies themselves which immunospecifically bind to antibodies that recognize oligosaccharide epitopes of *N. gonorrhoeae* which are not present in human blood group antigens and a composition comprising the same. The fragments retain the antigen binding specificity and react with an idiotype that is directed against an oligosaccharide antigen of *N. gonorrhoeae*. The anti-idiotypic monoclonal antibody is produced by the hybridoma cell line HB 11311 deposited at the ATCC. See claims; paragraph bridging columns 3 and 4; column 5, lines 30-37; column 7, lines 41-46 and lines 55-60; sections II(a) and II(b) in columns 21 and 22; and third and fourth paragraphs in column 28. That the prior art binding fragments intrinsically serve as peptide mimics is inherent from the teachings of Rice *et al.* Rice's ('067) whole anti-idiotypic antibody comprising the binding fragment is viewed as the multiple antigen peptide.

Claims 1, 3 and 9-15 are anticipated by Rice *et al.* ('067).

16) Claims 1, 3 and 9-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rice *et al.* (US 5,476,784) ('784).

Rice *et al.* ('784) disclosed fragments of anti-idiotypic antibodies and antibodies themselves which immunospecifically bind to antibodies that recognize oligosaccharide epitopes of *N.*

gonorrhoeae which are not present in human blood group antigens and a composition comprising the same. The fragments retain the antigen binding specificity and react with an idiotype that is directed against an oligosaccharide antigen of *N. gonorrhoeae*. The anti-idiotypic monoclonal antibody is produced by the hybridoma cell line HB 11311 deposited at the ATCC. See claims; paragraph bridging columns 3 and 4; column 5, lines 30-37; column 7, lines 41-46 and lines 55-60; sections II(a) and II(b) in columns 21 and 22; and first and second paragraphs in column 29. That the prior art binding fragments intrinsically serve as peptide mimics is inherent from the teachings of Rice *et al.* Rice's ('784) whole anti-idiotypic antibody comprising the binding fragment is viewed as the multiple antigen peptide.

Claims 1, 3 and 9-15 are anticipated by Rice *et al.* ('784).

17) Claims 1-3, 10-13 and 15 are rejected under 35 U.S.C. § 102(a) as being anticipated by Ngampasutadol *et al.* (*In*: *Abstracts of the Eleventh International Pathogenic Neisseria Conference*, (Ed) Nassif X *et al.* Nice, France, 1998, p. 159) as evidenced by Rice *et al.* (US 5,476,784) ('784).

It is noted that the applied prior art reference is a disclosure by 'another' as it is co-authored by T.G. Graf, T.F. Smith and J. Sharon, and therefore qualifies as prior art under 35 U.S.C. § 102. The phrase "for immunizing against *N. gonorrhoeae* infection" in claim 15 is viewed as being directed to the intended use of the claimed product.

Ngampasutadol *et al.* disclosed a peptide mimic as a potential vaccine candidate having the consensus amino acid sequence, DE-GLF, which mimics the oligosaccharide epitope of the 2C7 monoclonal antibody which epitope is a widely expressed gonococcal oligosaccharide epitope. The peptide mimic inhibits the binding of 2C7 monoclonal antibody to gonococcal LOS. See entire document. That Ngampasutadol's 2C7 monoclonal antibody is produced by a hybridoma cell line having the characteristics of HB 11311 as deposited at the ATCC is inherent from the teachings of Ngampasutadol *et al.* in light of what was known in the art at the time. For instance, Rice *et al.* ('784) provided such a disclosure (see second and third paragraphs in column 29).

Claims 1-3, 10-13 and 15 are anticipated by Ngampasutadol *et al.* Rice *et al.* ('784) is **not** used as a secondary reference in combination with Ngampasutadol *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Ngampasutadol *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

Rejection(s) under 35 U.S.C. 103

18) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

19) Claims 1-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ngampasutadol *et al.* (*In*: *Abstracts of the Eleventh International Pathogenic Neisseria Conference*, (Ed) Nassif X *et al.* Nice, France, 1998, p. 159) and Tam (In: Peptide Antigens: A Practical Approach. (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, 1993, pp. 83-90).

The teachings of Ngampasutadol *et al.* are explained above which do not disclose the peptide mimic comprising cysteine termini, an adjuvant, or a protein carrier, or being present as a multiple antigen peptide.

However, it was routine and conventional in the art at the time of the invention to add cysteine residues one at each terminus of a peptide epitope in order to protect the peptide from modification and to effect polymerization via disulfide formation. It was also routine and conventional to modify a peptide as a multiple antigen peptide with a built-in-adjuvant for the purpose of providing a very high density of the peptide epitope. For instance, see the teachings of Tam on pages 87, 83 and 84.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add Tam's cysteine residues at each terminus of Ngampasutadol's DE-GLF peptide mimic, and/or modify Ngampasutadol's DE-GLF peptide mimic as a multiple

antigen peptide with a built-in-adjuvant as taught by Tam to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of protecting Ngampasutadol's DE-GLF peptide mimic from modification and to advantageously effect polymerization via disulfide formation as taught by Tam, and/or to modify or present Ngampasutadol's DE-GLF peptide mimic as a multiple antigen peptide with a built-in-adjuvant for the purpose of advantageoulsy providing a very high density of the peptide mimic as taught by Tam.

Claims 1-15 are *prima facie* obvious over the prior art of record.

20) Claims 1 and 3-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rice *et al.* (US 5,476,784) ('784).

The teachings of Rice *et al.* ('784) are explained above which do not disclose the peptide mimic comprising cysteine termini, an adjuvant, or a protein carrier, or being present as a multiple antigen peptide.

However, it was routine and conventional in the art to add cysteine residues one at each terminal of a peptide epitope in order to protect the peptide from modification and to effect polymerization via disulfide formation. It was also routine and conventional to modify a peptide as a multiple antigen peptide with a built-in-adjuvant for the purpose of providing a very high density of the peptide epitope. For instance, see the teachings of Tam on pages 87, 83 and 84.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add Tam's cysteine residues at each terminus of Rice's ('784) peptide mimic, and/or modify Rice's ('784) peptide mimic as a multiple antigen peptide with a built-in-adjuvant as taught by Tam to produce the instant invention, with a reasonbale expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of protecting Rice's ('784) peptide mimic from modification and to advantageoulsy effect polymerization via disulfide formation as taught by Tam, and/or to modify or present Rice's ('784) peptide mimic as a multiple antigen peptide with a built-in-adjuvant for the purpose of advantageoulsy providing a very high density of the peptide mimic as taught by Tam.

Claims 1 and 3-15 are *prima facie* obvious over the prior art of record.

Remarks

21) Claims 1-15 stand rejected. Claim 16 is free of prior art currently of record and therefore is allowable.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Febuary, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER